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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/578,903

01/08/2007

Richard Head

024219-0105

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SUITE 500  
3000 K STREET NW  
WASHINGTON, DC 20007

EXAMINER

YU, HONG

ART UNIT

PAPER NUMBER

1616

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DELIVERY MODE

03/03/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/578,903	<b>Applicant(s)</b> HEAD ET AL.	
	<b>Examiner</b> HONG YU	<b>Art Unit</b> 1616	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 October 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5 and 7-17 is/are pending in the application.
- 4a) Of the above claim(s) 1-4 and 9-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5, 7, 8 and 15-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Status of claims*

The amendment file on 10/30/2009 is acknowledged. Claim 6 has been canceled, claims 1-4 and 9-14 have been withdrawn, and new claims 15-17 have been added. Claims 5, 7, 8, and 15-17 are under examination in the instant office action.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

***Claims 5, 7, 8, 15, 16, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Sair et al. (US 4,230,687).***

Sair et al. meets all of the limitations of claims 5, 7, 8, and 15. Sair et al. discloses an encapsulation material comprising casein as a protein and modified starch Capsul as a treated carbohydrate (claim 1 and column 9, line 24-28). Sair et al. is silent about the modified starch as carbohydrate being treated to make emulsions of the encapsulation material stable and to increase the number of sugar reducing groups in the carbohydrate. The treated carbohydrate recited in the disclosure of the instant specification is Capsul (page 7, line 30) which is the same as the modified starch (Capsul) disclosed by Sair et al., thus the modified starch disclosed by Sair et al. is

Art Unit: 1616

necessarily treated to make emulsions of the encapsulation material stable and to increase the number of sugar reducing groups in the carbohydrate. Sair et al. is silent about the encapsulation material releasing the therapeutic and nutritional agents in predetermined location in the gastro-intestinal tract. The encapsulation material disclosed by Sair et al. comprises the same components as the encapsulation material recited in the instant claim, thus the encapsulation material disclosed by Sair et al. would necessarily possess the same release property as that of the encapsulation material recited in the instant claim.

Sair et al. meets all of the limitations of claim 16. Sair et al. discloses the said encapsulation material being dried to form powder (column 24, line 52 and 53).

Sair et al. meets all the limitations of claim 17. Sair et al. discloses a method of making encapsulation material comprising dissolving casein in water then mixing the casein solution with essential oil (example 4: column 12, line 40-51). Although the method of making the encapsulation material disclosed by Sair et al. is different from the method of making the encapsulation material recited in the instant claim; the instant claim is a product-by-process claim. The determination of patentability of a product-by-process claim is based on the product itself, not its method of production. If the product in the product-by-process claim is the same or obvious from a product of the prior art, the claim is unpatentable even though the prior art product was made by a different process. Both of the encapsulation material disclosed by Sair et al. and the encapsulation material recited in the instant claim comprise the same components with the components being physically mixed, thus the product disclosed by Sair et al. would

Art Unit: 1616

necessarily be the same as the product recited in the instant claim. The burden is shifted to the applicant to provide evidence to demonstrate that the structure of the claimed encapsulation material resulted from the said process is different from that of the encapsulation material disclosed in the prior art. See MPEP 2113 [R-1].

### ***Response to Arguments***

Applicant's arguments, filed on 10/30/2009, have been fully considered but they are moot in view of new ground of rejections.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hong Yu whose telephone number is 571-270-1328. The examiner can normally be reached 8:50-5:20 Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Art Unit: 1616

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. Y./

Examiner, Art Unit 1616

/Johann R. Richter/

Supervisory Patent Examiner, Art Unit 1616